

**REMARKS**

Claims 35-54 are pending.

**DOUBLE PATENTING REJECTION**

Claims 35-38 are rejected on the ground of non-statutory obvious-type double patenting over claims 1 and 4 of US Patent No. 6,358,924. Applicant inadvertently did not include the terminal disclaimer in their previous response. Applicant herewith submits a terminal disclaimer over US Patent No. 6,358,924. As such, Applicant submits the rejection is moot and requests withdrawal.

**35 U.S.C. 112 REJECTION**

Applicant submits that the present rejection is ambiguous. The Examiner alleges that Claims 35-54 are rejected under 35 U.S.C. 112, first paragraph as failing to comport with written description. The Examiner has set forth an analysis discussing the factors set forth in *In re Wands*. (858 F.2d 731, 737). Applicant submits that such an analysis is appropriate for a rejection under the enablement requirement of 35 U.S.C. 112, first paragraph and not for written description. The written description requirement is separate and distinct from the enablement requirement. *Vascath, Inc., v Mahhurkar*, 935 F.2d 1555, 1563. Applicant will address the Examiner's concerns with respect to written description.

The Examiner appears to allege that the Applicant has described the terms "GLP-1, GLP-1 analogs and GLP-1 derivatives" by function and not the structure of the compounds. (Page 4-5, Paper No.20070615)

To satisfy the written description requirement, "the disclosure must convey must . . . convey with reasonable clarity to those skilled in the art that . . . [the inventor] was in possession of the invention." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d. 1320, 1323.

Applicant respectfully submits the application complies with the written description requirement as Applicant has provided sufficient disclosure of actual GLP-1 analogs and derivatives, (not mere functional definitions) to convey with reasonably clarity that the Applicants were in possession of the claimed invention.

The present invention is directed to a formulation comprising GLP-1, GLP-1 analogs and GLP-1 derivatives, a tween polymeric surfactant, a buffer and a preservative. Applicant has defined these terms using structural features starting on page 7, line 19. For example, GLP-1 analogs are defined as having “one or more amino acid substitutions, deletions, inversions, or additions compared to GLP-1.” (Specification, page 7, lines 24-26). In addition, pages 7-12 provide examples of many GLP-1 analogs and derivatives. Specifically, page 9, line 26 through page 10 discloses a specific large genus of GLP-1 analogs which can also be derivatized. Thus, the Applicant has not merely relied on functional definitions to describe the terms “GLP-1, GLP-1 analogs and GLP-1 derivatives.” Applicant has provided structural information in defining these terms and thus, Applicant submits, the written description requirement has been met.

### **Conclusion**

Applicant believes that the rejections submitted by the Examiner have been traversed and respectfully ask that the Examiner allow all pending claims.

Respectfully submitted,

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